Centrale Commissie Mensgebonden Onderzoek

# CCMO: CTIS Tips and Tricks

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# Trial category and relevant document publication timelines

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# Trial category and relevant document disclosure timelines

1. Determine which category is applicable for the trial. This is dependent on the trial type.

| Category | Trial type |
|---|---|
| Category 1<br>Pharmaceutical development clinical trials | Phase I clinical trials in healthy volunteers or patients<br>Phase 0 trial in healthy volunteers or patients<br>Bioequivalence and bioavailability trials<br>Similarity trials for biosimilars<br>Equivalence trials for combination or topical products |
| Category 2<br>Therapeutic exploratory & confirmatory clinical trials | Phase I and phase II integrated clinical trials<br>Phase II clinical trials<br>Phase II and phase III integrated clinical trials<br>Phase III clinical trials |
| Category 3<br>Therapeutic use clinical trials | Phase III and phase IV integrated clinical trials<br>Phase IV clinical trial and low interventional trials |

2. Depending on the trial category, certain documents will become publicly accessible. See Table I and II of the Annex I Guidance Document for an overview of the published structured data and documents as well as relevant disclosure timelines. In order to protect commercially confidential information (CCI) and/or personal data, a document with redactions ("**For Publication**") and a document without redactions ("**Not for Publication**") can be uploaded in CTIS. Documents not in this list will not be publicly accessible.
For more information, see the Revised CTIS transparency rules.

**Table II – CTIS Documents 'for publication' and relevant disclosure timelines**

The detailed list of documents that are, or are not subject to publication is specified in documents on CTIS application fields and Notification and Results. Disclosure timelines are provided in this table, and modalities in table IV (including exceptions applicable to 'historical trials').

**Caution: any document inadvertently uploaded 'for publication' into the below document upload sections will be published.** Example: if an IB is uploaded into the SmPC section of a Cat 2 or 3 trial, the IB will be made public if not corrected by the sponsor before the decision on the application.

| **Documents**[4]<br>*to be submitted in two versions 'for publication' and 'not for publication* | **Publication timelines**[5] | | |
|---|---|---|---|
| | **Category 1** | | **Category 2 and 3**<br>*including integrated ph1&2* |
| | Paediatrics and/or PIP | Adults | |
| **Protocol**, *including patients facing documents*[6] | Upon results' submission | 30 months after EU/EEA EoT | First MSC decision |
| **Protocol synopsis** | | | |
| **SmPC**, *if available* | Never | | That MSC decision |
| **Recruitment arrangements**, *including procedures for inclusion and copy of advertising material*[7] | | | |
| **Subject information** and **informed consent form** | | | |
| **Lay person summary of results** | As soon as submitted | 30 months after EU/EEA EoT | As soon as submitted |
| **Final summary of results**[8] | | | |
| **Clinical study report**, *if available*[9] | As soon as submitted | | |

[4] Table III lists the type of personal data generally contained in documents 'for publication', while for an indicative list of documents that are not published: see table VI
[5] To know the type of trials belonging to each Category, refer to table V
[6] Protocol: this is referred to any kind of protocol (including master protocol, sub-protocol, etc.); patients facing documents: see definition in Clinical Trial Regulation 536/2014 Q&A
[7] Recruitment arrangements: provide a clear indication of what the first act of recruitment is; advertising material: this includes any printed materials and audio or visual recordings

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# How to **Upload** a Document in CTIS

“For Publication” and “Not For Publication” Documents

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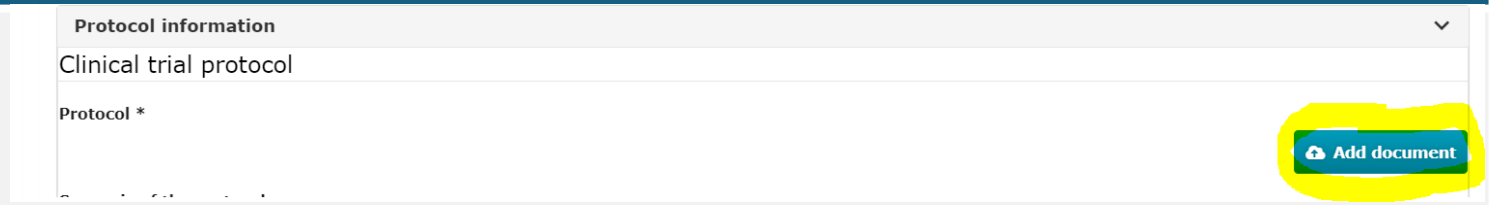
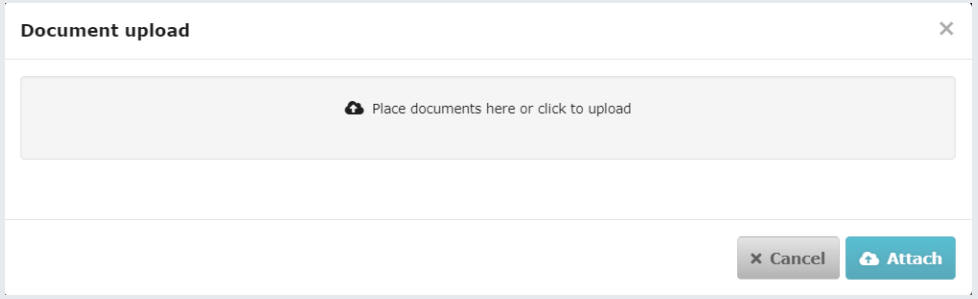
# Uploading Documents: For Publication and Not for Publication

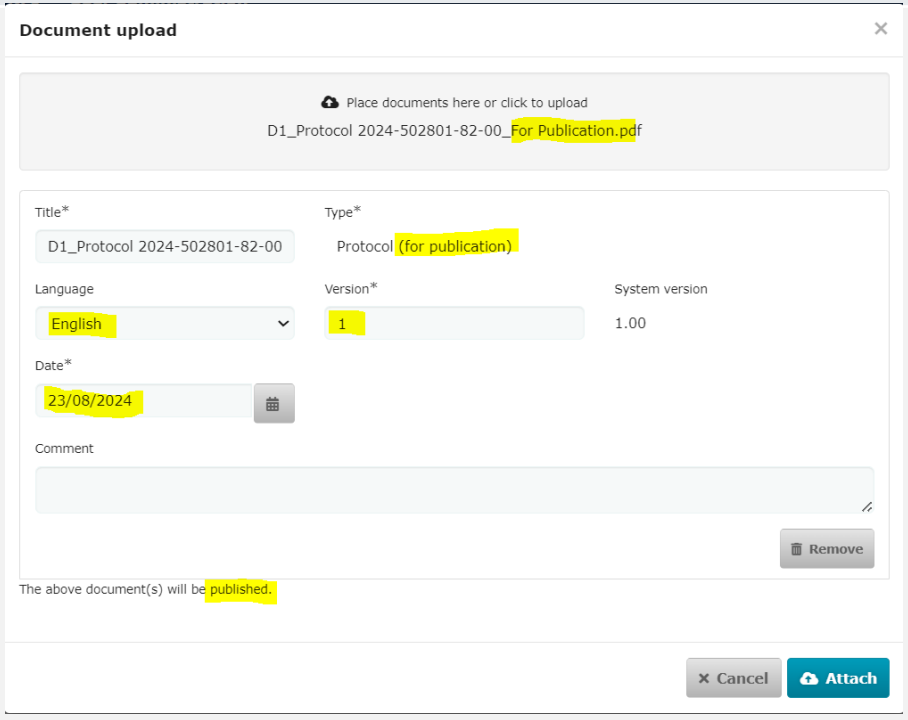
1. Click on “Add document”.




2. Drag or upload the document to CTIS. Always add the document intended for publication (with redactions) to CTIS first.



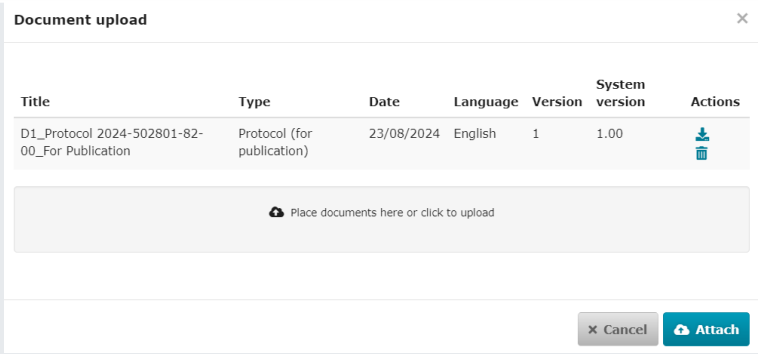

3. Check that the document intended for publication is uploaded in the “For Publication” placeholder. If needed, update the document title to comply with the CTCG best practice guide naming of documents).
Update the language, version and date. The language, version and date inputted into CTIS should match the language, version and date in the document itself.
Then click Attach.



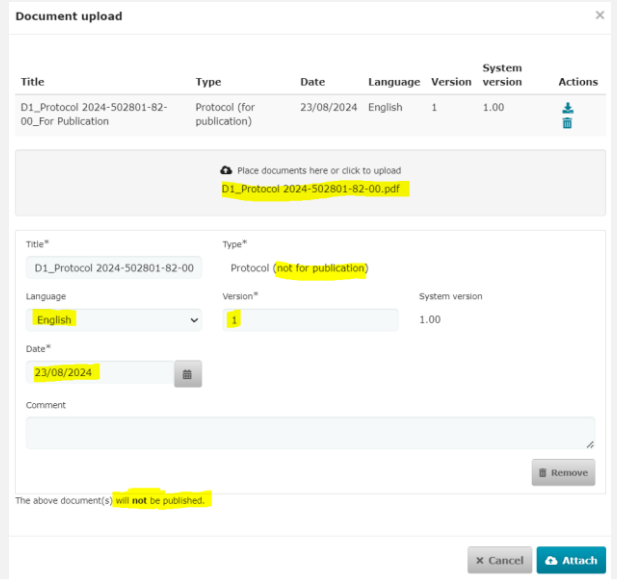
# Uploading Documents: For Publication and Not for Publication CONTINUED...

4. To upload the “Not for Publication” version of the same document, click on (⊕ Add) icon found next to the “For Publication” version of the document.


5. Drag or upload the document to CTIS. This time, add the “Not For Publication” version (without redactions) to CTIS. Please note, the “Not For Publication” version is not required if there are no redactions in the “For Publication” version.




6. Check that the document intended as not for publication is uploaded in the “Not For Publication” placeholder. If needed, update the document title to comply with the CTCG best practice guide naming of documents). Update the language, version and date. The language, version and date inputted into CTIS should match the language, version and date in the document itself.
Then click attach.



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# How to **Upload** a Document in CTIS

Documents not publicly accessible

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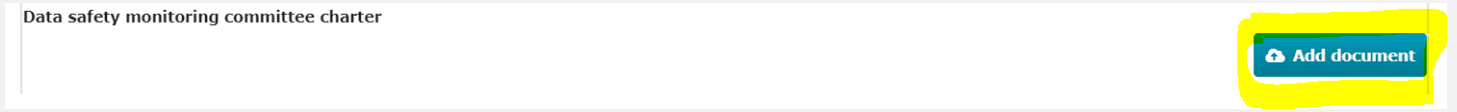
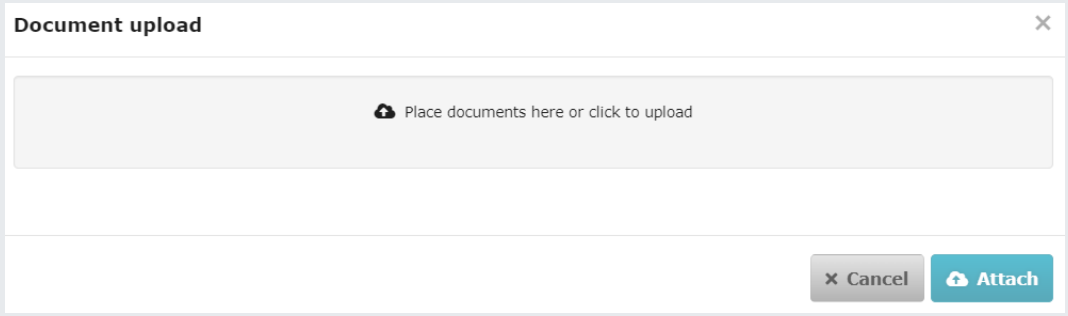
# Uploading Documents: Not Publicly Accessible

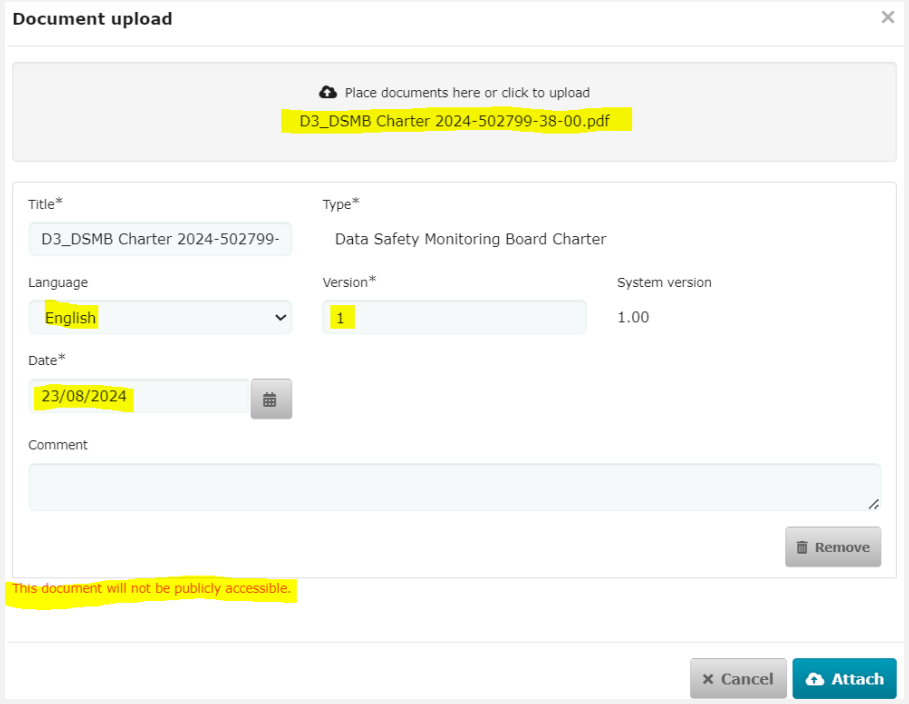
1. Click on “Add document”.




2. Drag or upload the document to CTIS.
This document will not be publicly accessible so only a version without redactions is required.




3. Check that the document is uploaded in a placeholder that will not be publicly accessible. If needed, update the document title to comply with the CTCG best practice guide naming of documents).
Update the language, version and date. The language, version and date inputted into CTIS should match the language, version and date in the document itself.
Then click Attach.



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# How to **Update** a Document in CTIS

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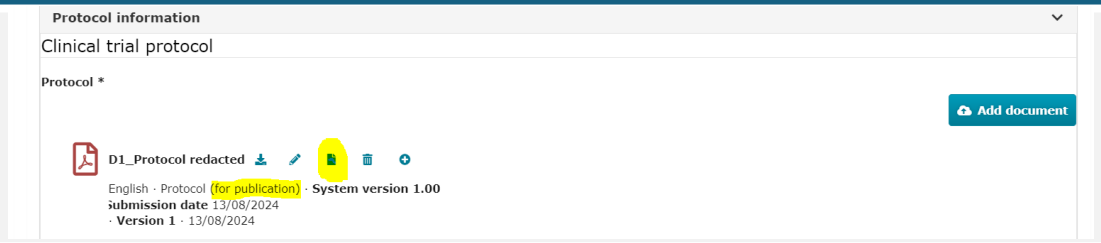
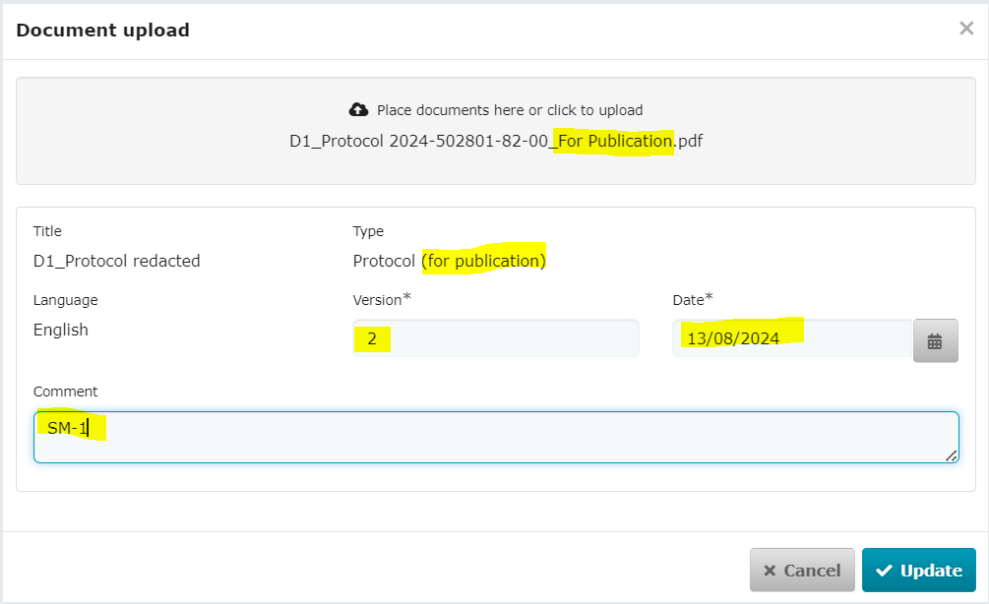
# Updating Documents

1. Click on the symbol ( Update) found next to the previous “For Publication” version of the document. This will allow you to update the “For Publication” version of the document.




2. Drag or upload the document to CTIS. The name of the previous document will remain the name of the new document.
Update the version and date. The version and date inputted into CTIS should match the version and date in the document itself.
Then click update.




3. Follow the same instructions for the “Not for Publication” version of the document as well as for the documents that are not publicly accessible.
When updating redacted documents that are publicly accessible (such as the protocol or ICF), remember to update and upload both the “For Publication” and “Not for Publication” versions.

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# RFI instructions

Applying changes and submitting the RFI Response

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# RFI instructions for sponsors

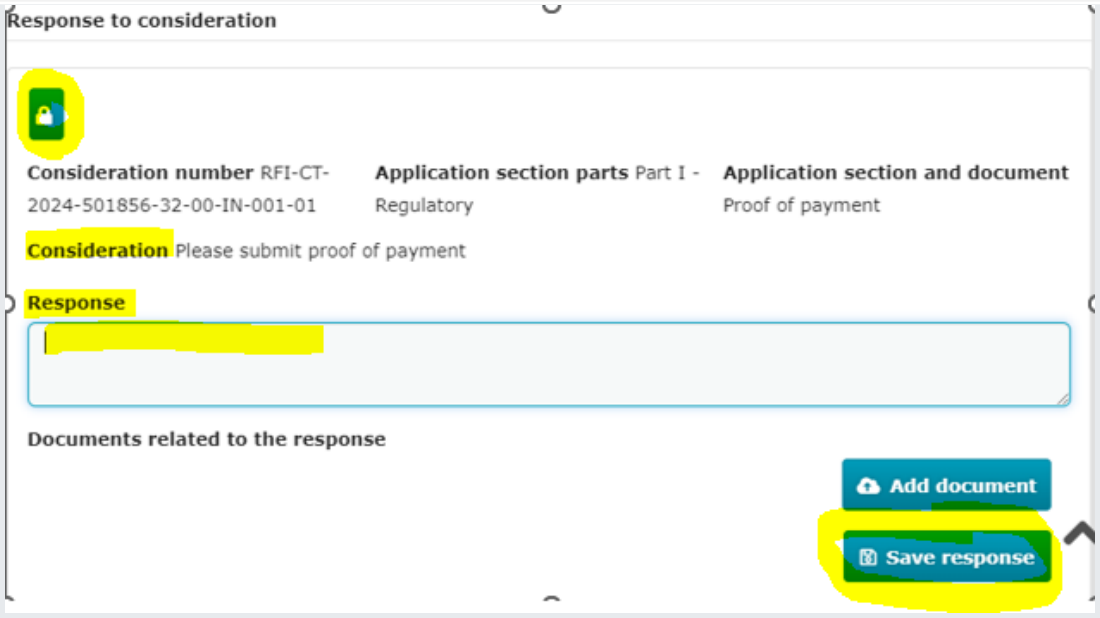
1. Navigate to the RFI in the Evaluation section, under the correct part (Validation, Part I or Part II).

Open the RFI by clicking the lock (closed lock = available for editing). Make sure to submit the RFI Response by the indicated Due Date, otherwise the application will lapse and cannot continue.


2. Scroll down to see the considerations within the RFI. Each consideration contains a lock button. After closing the lock, a textbox will appear to enter a written response, which is mandatory.

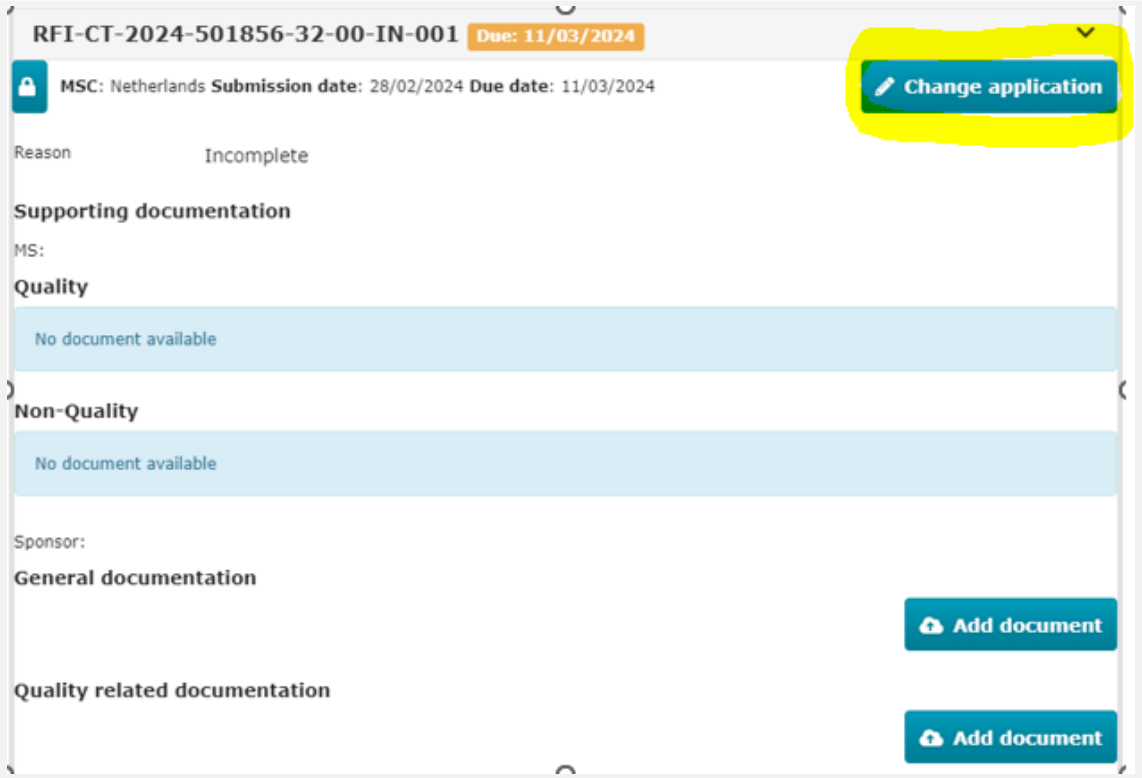
After the written response has been entered, click ‘Save response’, which will open the lock again. This should be repeated for each consideration.

The purpose of the optional ‘Add document’ button is NOT to upload the requested documents but can be used to submit the response to that particular consideration as a document. In practice, it is rarely used.



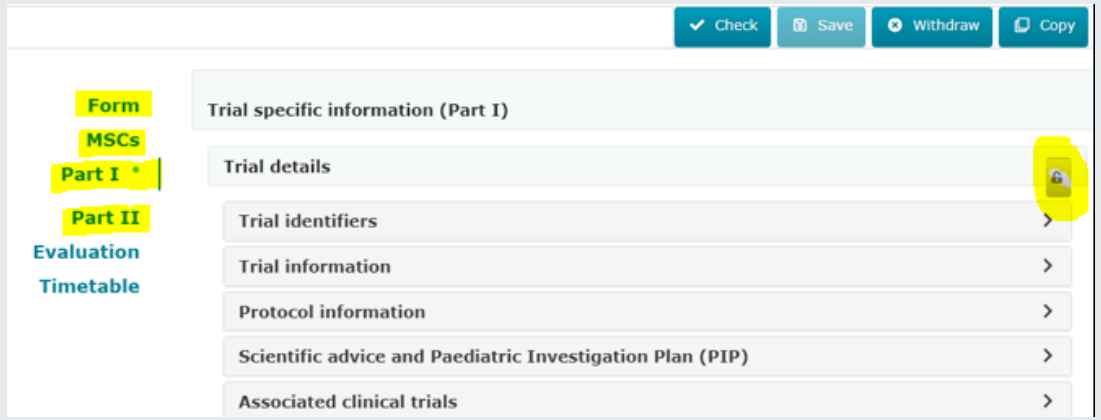
# RFI instructions for sponsors CONTINUED...

3. If changes to the application (new documents, modified documents, changes to the data fields) are requested in the RFI, then these can be applied via the ‘Change application’ button at the top-right corner of the RFI.



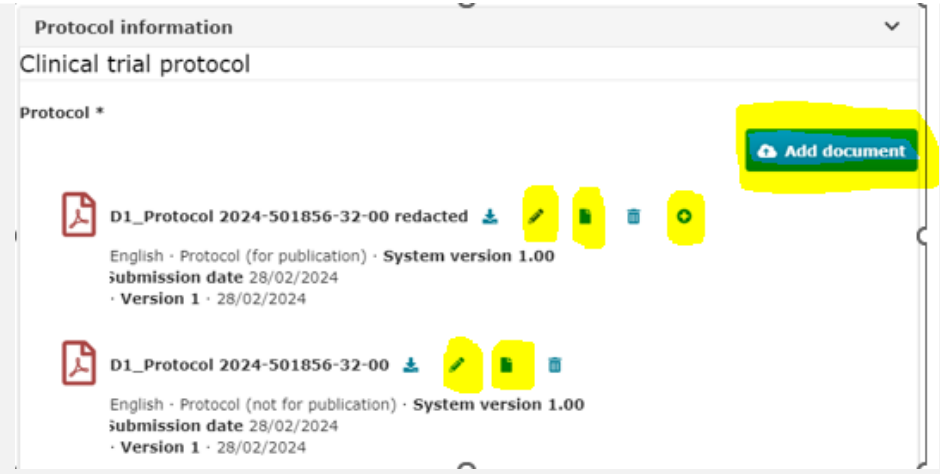

Please note: documents requested in the RFI should NOT be uploaded within the RFI itself. The two ‘Add document’ buttons are optional, and only serve to upload documents containing the RFI Response.

4. Clicking the ‘Change application’ button will lead you to the application, and unlocks the application for applying changes. The editing functionality will be activated, similar to when the application was first created. Close the lock of the section where changes need to be made, to allow changes to that section.



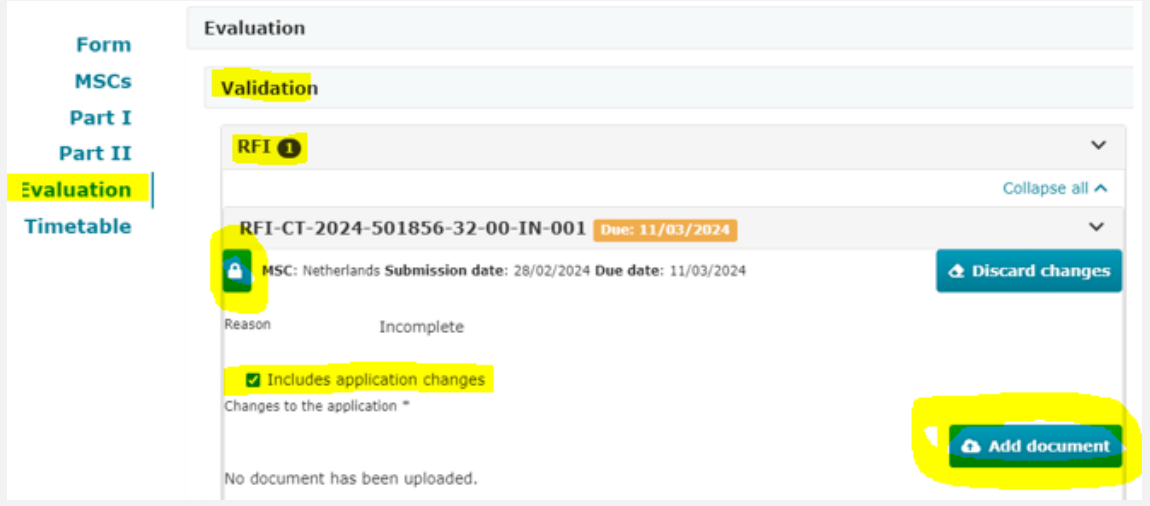
# RFI instructions for sponsors CONTINUED…

5. The second symbol beside each document ( Edit) is used to edit the title, version or date of an existing document.
The third symbol ( Update) is used to upload a new version of that document. You will be asked to enter the new version number and document date.
The fifth symbol ( Add) only appears for documents in ‘For Publication’ slots and is used to upload the “Not for Publication” version of that document.
The blue ‘Add document’ button is used to upload new documents.




6. After all requested changes have been applied, open all locks again, and return to the evaluation environment by clicking ‘Evaluation’ on the left.

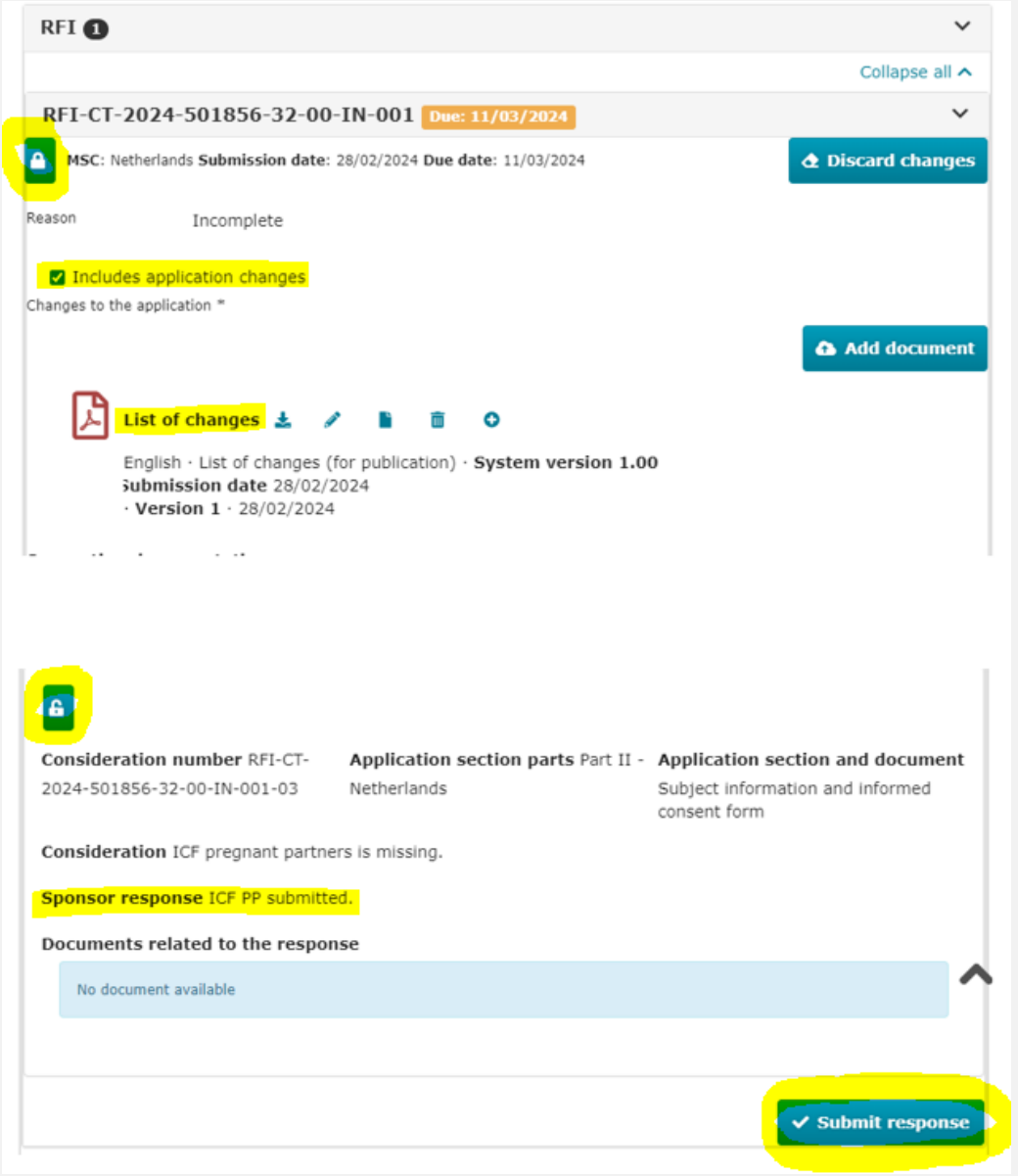

7. Nagivate to the RFI that is being addressed, in this example this is the validation RFI. Click the lock again to close it.
Keep the box ‘Includes application changes’ checked.
A mandatory *RFI Response List of Changes to the Application document* should be uploaded via the ‘Add document’ button.
This document should describe all changes to the application in detail: provide a clear list of all new documents (title, version, date) and changes to data fields.



# RFI instructions for sponsors CONTINUED...

8. Finally, the RFI Response can only be submitted if:

- The RFI master lock in the top-left corner is closed, and
- The list of changes document has been uploaded, and
- A written response has been entered for all considerations, and
- The locks of all individual considerations are opened.



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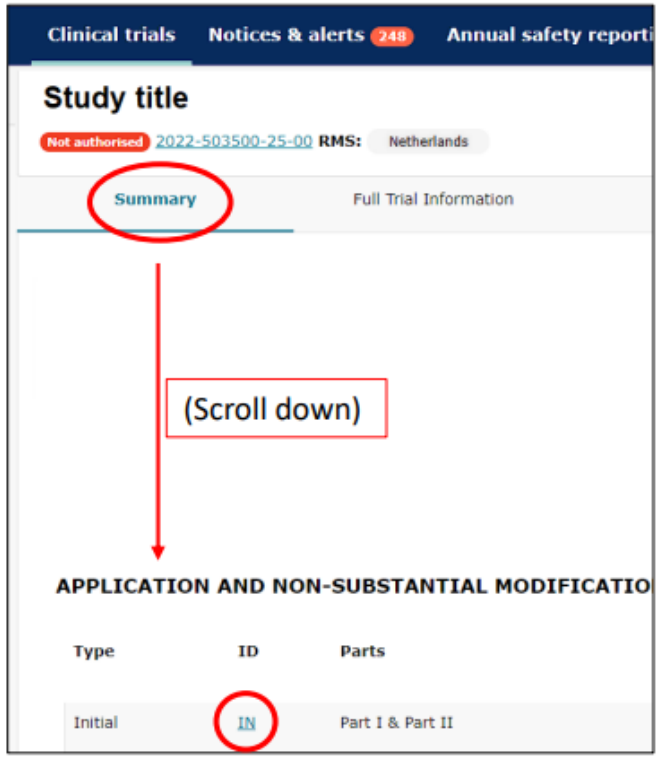
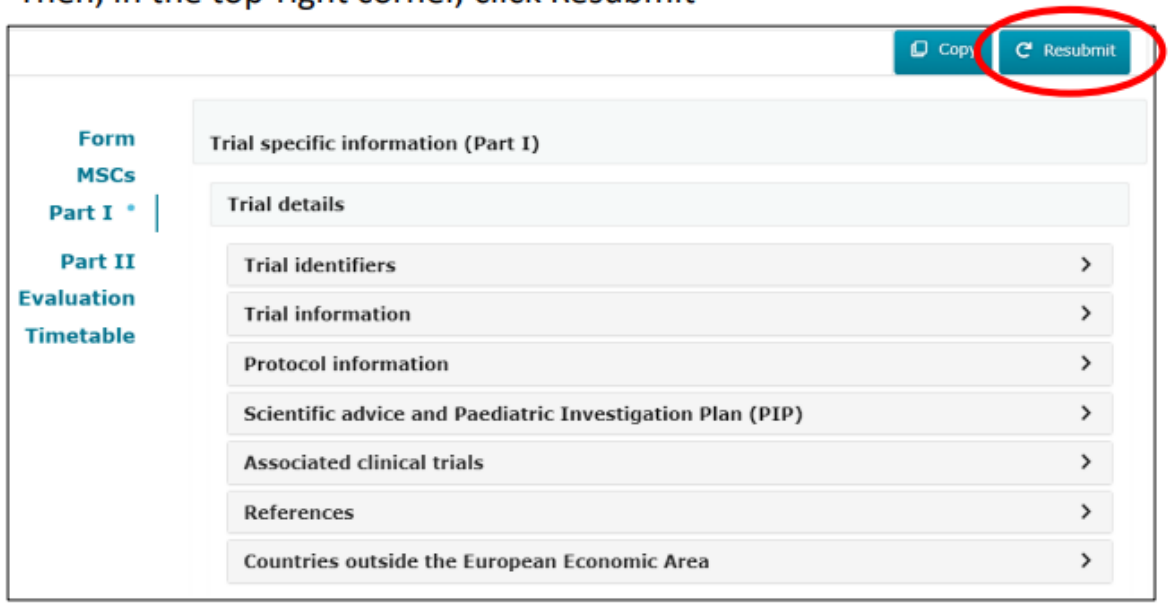
# Resubmission of an application

# Resubmission

Applications that lapsed (sponsor misses RFI response deadline), were withdrawn by the sponsor, or received a negative validation (Not Valid) or a negative decision (Not Authorised), can be resubmitted.
On the clinical trial page, in the Summary tab, scroll down to the application overview. Click the application you want to resubmit.




Then, in the top-right corner, click Resubmit




The documents of the original submission will be copied to the resubmission. Documents can be replaced if necessary (e.g. cover letter).
Please note: the version and date of all documents is reset to v1 and today, so click Edit (pencil icon) to enter the correct version and date for all documents. The resubmission will keep the original CT-number, but ending with -01.